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IN THE
Supreme Court of the United States
OCTOBER TERM, 1991

GENETICS INSTITUTE, INC.,
and CHUGAI PHARMACEUTICAL CO., INC.,
Petitioners,

v.

AMGEN, INC.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF AMICUS CURIAE OF THE COUNCIL FOR RESPONSIBLE GENETICS IN SUPPORT OF PETITIONERS

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BRIEF AMICUS CURIAE OF THE COUNCIL FOR RESPONSIBLE GENETICS IN SUPPORT OF PETITIONERS

INTEREST OF *AMICUS CURIAE* *

The Council for Responsible Genetics is a national organization of scientists, public health advocates, environmentalists, and concerned citizens, dedicated to ensuring that biotechnology is developed safely and in the public interest. Founded in 1983 as the Committee for

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* Consent of all parties has been granted to file this brief of Amicus Curiae in support of petitioners. Letters of Consent have been filed fith the Clerk of the Court.

Responsible Genetics, the Council's activities are based on the principle that an informed public can and must be involved in setting the direction for emerging technologies. The Council monitors developments in biotechnology in the United States and abroad, and its work is concentrated in three major areas: public participation in decisions about the use of genetically engineered organisms, the use and possible misuse of predictive genetic tests, and the promotion of the peaceful use of biomedical research in view of the dangers and risks of chemical and biological weapons. The Council regularly provides technical assistance and testimony to Executive and Congressional bodies, produces *geneWATCH*, the only bimonthly reporting the social, political, and ethical impact of new genetic technologies, and recently produced the book, *Preventing a Biological Arms Race*, published by MIT Press.

SUMMARY OF ARGUMENT

The Constitution and its patent clause, especially, embrace the principles of scientific inquiry. A benchmark of the world of science is the axiom that it is a self-correcting institution, a principle which is mirrored in the patent system's requirement of full disclosure. Without full disclosure, claims of new knowledge cannot be replicated and thus cannot be verified. The ability to verify and, if confirmed, improve upon new knowledge, including patented inventions, depends upon the full availability of the inventor's materials. In the field of genetic engineering, the deposit of newly engineered organisms is widely considered an absolute requirement. The Federal Circuit's scientifically untenable decision to continue the deposit of naturally-occurring organisms but to dispense with the deposit of genetically engineered organisms is bafflingly unsupportable and effectively rejects and violates the Congressional "best mode" doctrine.

ARGUMENT

I. THE PATENT CLAUSE[1] INCORPORATES THE SCIENTIFIC METHOD AS THE MEANS TO PROMOTE PROGRESS THROUGH THE DIFFUSION OF USEFUL SCIENTIFIC KNOWLEDGE

The Founders understood that science was as much a social as a natural phenomenon, and the principles of the patent system they presciently authorized, when properly executed, allow the self-correcting features of the scientific method to operate efficiently.[2] That efficiency can, in part, be attributed to the extraordinary care with which the patent clause was drafted and, in part, to the influence of Jefferson who, indeed, has been called "the father of patent law in this country."[3] This Court has noted the foresight of the patent clause and its incorporation of Jefferson's belief that the patent system should be a partner of science in the advancement of human knowledge.[4]

Twentieth-century science, though organized in far greater complexity, is even more clearly a social activity. Through its rigorous methods, it constantly tests and retests apparently known facts to redraw our notions of re-

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[1] "The Congress shall have power . . . to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." *U.S. Const.*, art. I, § 8, ch. 8.

[2] "Scientific inquiry is self-correcting; fabricated or erroneous data are exposed when their irreproducibility or inconsistency with established observation is discovered." Grouse, Editorial, J. A.M.A. 248:1637-1638 (1982).

[3] "This represents rather detailed constitutional language for our Constitution. After all our laconic forefathers only used seven words—'to regulate commerce . . . among the several states . . .'—in order to create the enormous interstate commerce power." *Bepex Corp. v. The Black Clamson Company*, 713 F.2d 202, 204 (6th Cir. 1983).

[4] *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 9 (1968).

ality more accurately and usefully. As a social system, it is self-correcting by virtue of its openness, which, at its best, allows all its participants to learn, assess, challenge, and ultimately confirm or reject the apparent facts of discoveries both new and old. When carefully policed, the principles of our patent system, astonishingly so after two centuries, continue to be a useful tool of the scientific method. As a social enterprise, science, and the knowledge it produces, depends profoundly upon the free availability of fully disclosed knowledge, derived from the patent system and elsewhere, in order to confirm or reject, through replication, claims of discovery.

The patent clause's ultimate dependence upon full disclosure to produce the "progress" of which it speaks has been recognized, by this Court, Congress, and others, time and again.[5] Without full disclosure, the replication upon which the scientific method relies can not even begin. The panoply of legislative safeguards contained within the Patent Act almost uniformly guarantee disclosure. From the distinction between "idea" and "application," which forbids the misuse of the patent system to suppress basic knowledge [6] to the "best mode" requirement,[7] the Patent Act is replete with safeguards assuring that legitimate patents serve only to disseminate, not monopolize, knowledge itself. It has been observed that "patent law parallels and reinforces the scientific community's replicability norm." [8]

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[5] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156 (1989).

[6] *Parker v. Flook*, 437 U.S. 584 (1978).

[7] 35 U.S.C. § 112.

[8] Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," 97 Yale L.J. 177, 213 (1987).

The Founders, perhaps in the spirit of their times,[9] perhaps anticipating today's technological age, authored a document which embraces and, even more, promotes, the scientific method itself.[10] Jefferson, it is said, thought the world of science and that of his new Constitution to be virtually one and the same.[11] But while the constitutional plan, in large part, embraces the scientific method, the patent scheme often anticipates it, demanding even more than that required by scientific norms. This is nowhere more true than in the patent law's disclosure requirements, including the "best mode" doctrine, for "[t]he 'best mode' requirement goes beyond the scientific community's replicability norm." [12] In disregard of that principle, the Federal Circuit's decision in this case, by dispensing with the deposit requirement, cavalierly adopts a norm less demanding than that of the scientific community which it seeks to promote. For the first time, it violates the principle by which the patent system, offering more than what science itself can and perhaps ever should—a monopoly over its fruits—traditionally imposes even more stringent requirements. Certainly, in no event, given the stakes, can patent law afford to demand *less* than the norms of the scientific community.

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[9] "The general view mantains that many of the founders shared the enthusiasm of the Enlightenment for scientific endeavors." Francione, "Experimentation and the Marketplace Theory of the First Amendment," 136 U. Pa. L. Rev. 417, 504 (1987).

[10] "There is no field of investigation, no meritorious research question, no generally recognized mode of inquiry in science today which is either so esoteric or so culture-bound by contemporary standards that their collective wisdom [was] unable to comprehend it." I. Carmen, Cloning and the Constitution: An Inquiry Into Governmental Policymaking and Genetic Experimentation (1985).

[11] "In Jefferson's reality, the worlds of science and public welfare were evidently one. Truth and freedom went hand in hand." I. Carmen, *id.*

[12] Eisenberg, *supra* n.8.

II. THE DEPOSIT OF BIO-ENGINEERED ORGANISMS IS ESSENTIAL TO BIOMEDICAL PROGRESS

At the outset, it should be clearly stated that this *amicus* takes no position here on the merits of patenting living organisms. But it is surely true that the view that living organisms should be included within the scope of the Patent Act, a view not necessarily shared by this *amicus*, makes the safeguards of the patent system more important than ever. In fact, the very basis of *Diamond v. Chakrabarty*[13] was that only Congress could alter the various rules of our patent system. What *Chakrabarty* stands for, above all, is that the judiciary cannot alter either the scope nor the safeguards of our patent laws.

It is axiomatic to genetic research that the deposit of genetically altered living organisms is essential. By virture of their very alteration, only a deposit of new cell lines can assure reproducibility. The reasoning of the Federal Circuit, which first distinguishes naturally-occurring from genetically altered cells, and then limits required deposits only to the former, would be scientifically laughable if it were not so socially disastrous. Clearly, the deposit of both kinds of organisms is important to "promote progress," as the patent clause mandates. But were one to make a choice between the two, it is unquestionable that deposit of genetically altered cells, not naturally-occurring ones, would be fundamental to satisfy the scientific method and the mandate of the Patent Act for full disclosure of an inventor's "best mode."

Scientifically speaking, the decision below is surprisingly regressive. Although the text of that decision shows no sign of it, the only really open *scientific* issue concerning genetic deposits is how and whether to document genetic changes in higher plants and animals. It has become virtually common knowledge in the scientific com-

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[13] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

munity and, in fact, in the lay community beyond it, that deposit is "routinely done for microorganisms." [14]

The reason deposit is so clearly required rests on the principle of availability which informs scientific research in every field. It mandates that disclosure of scientific results requires that all materials be made available to others. The rationales for availability stem generally from the "self-correcting" nature of science and emphasize three core norms: replicability, dedication, and progress.[15] The norm of replicability, which demands ac-

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[14] "In the case of genetically engineered organisms, however, it is often not possible to provide a sufficiently detailed, reproducible written description. But inventors have been creative in overcoming this technical obstacle by placing samples of the organisms in special depositories to become freely available after the patent issues. This is routinely done for microorganisms, but is much more difficult for plants and animals." Hoffman and Karny, "Can Justice Keep Pace With Science?, *The Washington Post*, April 10, 1988, at B3.

[15] "1. Replicability. Scientists should publish their research claims in a form that permits replication so that the scientific community can verify their claims: 'Once an experiment is published anyone should be able to reproduce it, otherwise it is worthless and might as well just not be published.' Replication requires access to the publishing scientist's unique materials.

2. Dedication. Publishing scientists should make their scientific advances available to the public: '[T]he act of publishing is the giving of a scientific advance to the public in a form which permits other scientists to reproduce the experiments . . . . [T]o withhold any necessary ingredient which is not generally available is morally equivalent to withholding essential information from the text of the publication and authors should in general be required to make available to other scientists those rare materials that go into the published experiments.' This dedication norm is violated by withholding essential information or rare materials that the author is able to supply.

3. Progress. Scientists should publish their research in a form that facilitates the progress of science: 'The work cannot be repeated or extended without the availability of the strain or cul-

cess, reflects the belief that only through replication can science verify new, as well as old, claims of discovery. The norm of dedication reflects the belief that the product of science is public property and the work of scientists belongs, first and foremost, to the society that supports it. The norm of progress reflects the belief that science is a means to a greater end, the advancement of the society of which it is a part.

The principle of availability means that deposit of microorganisms used in patented inventions is essential to allow others to fully benefit from the patent's disclosure. It means, in other words, that an inventor's "best mode" remains concealed until deposit is made. It is true that some have indeed suggested a modified deposit requirement but, importantly, only where "it is possible for another scientist to *faithfully duplicate* a process and thereby *consistently* achieve the *same* results as the original inventor. Thus, it may be possible to develop the microorganism based on the specification alone." [16] But in this case, and expressly so, others cannot "faithfully duplicate" the cells involved and cannot "consistently achieve the same results" for, as found at the trial level, others can only hope to achieve, "eventually," results that "could be better, . . . could be worse." (Opinion below, at 1211).

Upon the birth, or, more accurately, the manufacture, of the "Harvard mouse," still others have suggested relaxation of the deposit requirement with respect to higher animals, but only upon the condition that their full genetic

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ture.'" [Citations omitted]. Eisenberg, *supra* n.8, at 199 n.116. See also R. Merton, *The Sociology of Science*, 229-53 (1973).

[16] Schneider, "Note: Microorganisms And The Patent Office: To Deposit Or Not To Deposit, That Is The Question," 52 Fordham L. Rev. 592, 595 (1984) [Citations omitted] [Emphasis supplied].

materials be deposited.[17] That is, in fact, exactly what *amicus* urges in this case. For, in the case of microorganisms, deposit of the cell is the same as deposit of its genetic materials. It must be emphasized, therefore, that no one, except the Federal Circuit, has rejected a deposit requirement entirely.

While it may not always be necessary, therefore, to deposit naturally-occurring cells, it is, *as a matter of law*, inescapable that an inventor's "best mode" can *never* be accomplished without the deposit of genetically altered cells. This is, in fact, what Congress has required. For any fair reading of Section 112, requiring that the inventor set forth the best mode, and the realities of biomedical science, compels the conclusion that the clearly expressed aim of Congress—that inventors fully and completely disgorge the secrets of their invention—requires deposit, and sensibly so. The Federal Circuit's decision amounts to judicial legislation which, at least in this one decision, cuts to the very core of Congressional, and Constitutional, intent.

CONCLUSION

Both law and science are offended by the decision below. Biomedical science cannot serve its social purpose without the deposit of new microorganisms. The best mode requirement cannot be met, as a matter of law and scientific fact, without such deposit. The lower court's legally and scientifically unsupportable distinction between naturally-occurring and geneticaly engineered or-

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[17] "[T]he requirement of a deposit of genetic material serves as a guaranty that, as genetic engineering techniques become more advanced, the scientists of the future will have a store of material that will someday allow them to reproduce the mouse exactly. Most importantly, the genetic material deposit obviates the need for actual specimens of the mouse to be deposited, a practice that would quickly become untenable". Czarnetzky, "Note: Altering Nature's Blueprints For Profit: Patenting Multicellular Animals," 74 Va. L. Rev. 1327, 1360 (1988).

ganisms is, by its transparently artificial nature, evidence of the inadequate basis of its decision. Left unreviewed, that decision will inevitably breed a new form of patent law unforeseen by its Constitutional source and prohibited by its Congressional mandate.

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